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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,874	09/30/2003	Howard Bernstein	17976-0006	6790

  

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EXAMINER	
GEORGE, KONATA M	

  

ART UNIT	PAPER NUMBER
1616	

  

MAIL DATE	DELIVERY MODE
07/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/675,874

**Applicant(s)**

BERNSTEIN ET AL.

**Examiner**

Konata M. George

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/18/07</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-12 and 14-56 are pending in this application.

#### ***Request for Continued Examination (RCE)***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 18, 2007 has been entered.

#### ***Action Summary***

2. The examiner acknowledges the cancellation of claim 13. Therefore any and all rejections and/or objections directed to it are hereby withdrawn.
3. The rejection of claims 1-11, 14-35 and 37-56 under 35 U.S.C. 103(a) over Straub et al. is hereby withdrawn in view of applicants amendment to the claims.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. It is unclear to the examiner what these "derivatives" are (i.e. salts, ester, hydrates, etc.).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-12 and 14-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (US 4,818,542) in view of Straub et al (US 6,395,300).

Applicants claim a sustained release formulation comprising porous microparticles, which comprise a pharmaceutical agent and a hydrophobic matrix, wherein the microparticles have a geometric size of 0.1 to 5 microns and an average porosity of between 15% and 90% by volume.

***Determination of the scope and content of the prior art***

**(MPEP §2141.01)**

DeLuca et al. teach a porous microspheres for the controlled delivery of drugs or other matrix confined materials (col. 2, lines 51-54). Column 3, line 65 through column 4, line 36 teach that the porous microspheres are derived from copolymeric and homopolymeric polyesters such as, polyglycolic acid, polylactic acid, and copolymers of glycolide and L-lactide. Column 5, line 65 through column 6, line 1 teach that the microspheres can have a particles size of from between about 1 to 150 microns, but preferably between about 0.5 to 50 microns. Column 6, lines 2-31 teach that the agents are incorporated into the pores of the microparticles and that "agent" refers to and diagnostic or pharmacologically active agent, which would be generally suited for introduction into a human. Column 6, line 39 teaches that excipients can be incorporated in the formulation. Column 6, lines 48-52 teach that the composition is suitable for inhalation and by administering through the mucous membrane of the nose, throat or bronchiopulmonary tissue. Column 6, lines 58-62 teach that additional active agents can be incorporated in the drug delivery system. Column 6, line 67 through column 7, line 51 teach a method of making the particles by mixing the polymer solution and drug solution together, removing the solvent by a freeze-drying method, filtering and then air drying the particles. Column 8, lines 29-30 teach that surfactants can be employed in the composition.

***Ascertainment of the difference between the prior art and the claims***

**(MPEP §2141.02)**

DeLuca et al. do not teach the agent being released from the microparticles in the lungs for at least 2 hours as claimed or the average porosity volume of 5% to 90% by volume. DeLuca et al. do not teach the formulation comprising a bulking agent. It is for this that Straub et al. is joined.

Straub et al. disclose a porous drug matrix additionally comprising water-soluble polymers or sugars, wetting agents such as surfactants, etc. and the matrix having a diameter size of about 100 nm to 5 microns (col. 3, lines 46-61). Column 4, line 11 through column 8, line 9 list the types of drugs that can be employed in the drug matrix. Column 8, lines 34-67 teach examples of the polymers and sugars that can be used in the matrix such as polyvinylpyrrolidone (line 41), xylitol (line 59) and lactose (line 63). Column 11, line 47 through column 12, line 33 teach a method of making the porous drug matrix. Column 12, lines 46-67 teach examples of the surfactants to be employed in the matrix such as phospholipids like lecithins. Column 13, lines 29-41 teaches that the preferred embodiment of the invention is drug matrix in the form of a powder which can be reconstituted with an aqueous medium or using the powder formulation in a dry powder inhaler.

***Finding of prima facie obviousness***

***Rational and Motivation (MPEP §2142-2143)***

Although, prior art reference of DeLuca et al. do not teach the agent being released from the microparticles in the lungs for at least 2 hours as claimed by applicant, it is the position of the examiner that this limitation is inherent in the formulation as claimed. The composition as claimed is directed toward porous microparticles comprising a pharmaceutical agent and a matrix material. Since there is no additional information in the specification with regards to the release profile (i.e. coating or physical makeup which makes it a sustained release), any porous microparticle having the claimed drug and matrix material would have the release profile as claimed. The determination of the average porosity volume would have been obvious to one of ordinary skill in the art. One of ordinary skill in the art when formulating a porous particle for the sustained release of a drug would have determined that the amount of pores on the particles would have an effect on the delivery of the drug; the more pores the greater the delivery of the drug over a period of time; the less amount of pores, the less delivery of the drug over the same period of time.

Straub et al. is relied upon to teach that excipients such as bulking agents can be added to the composition of DeLuca et al. (col. 8, lines 10-12 and 59-63). Therefore, when looking for examples of excipients that can be used in porous microparticles, one of ordinary skill in the art could look to Straub et al. which teach a porous microparticle composition.

Art Unit: 1616

***Conclusion***

6. Claims 1-12 and 14-56 are rejected.

***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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